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EXAMINER	
MONDESI, ROBERT B	
ART UNIT	**PAPER NUMBER**
1652	

NOTIFICATION DATE	DELIVERY MODE
08/27/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/538,704	OLAYIOYE ET AL.	
	Examiner	Art Unit	
	Robert B. Mondesi	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26 and 33-48* is/are pending in the application.

4a) Of the above claim(s) *35 and 37-48* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26, 33-34 and 36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' election of Invention of Group VII, previously **claims 26-27**, now, **claims 26, 33-34 and 36** in response to the restriction requirement mailed April 18, 2007 is acknowledged. Because applicants did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Therefore the requirement is still deemed proper and is made FINAL.

Newly submitted **claims 35 and 37-48** directed to an invention that is independent or distinct from the invention originally claimed for the reasons: provided in the restriction requirement mailed April 18, 2007.

Accordingly, **claims 35 and 37-48** withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Status of the claims

Claims 1-25 and 27-32 have been canceled. **Claims 26 and 33-48** are pending. **Claims 35, 37-48** are withdrawn for pertaining to nonelected subject matter. **Claims 26, 33-34 and 36** are presently under examination.

Priority

The current application filed on February 21, 2006 is a 371 of PCT/AU03/01664 filed on 12/12/2003, which in turn claims priority to foreign application, AUSTRALIA 2002953341 filed on12/13/2002. A certified copy of foreign document AUSTRALIA 2002953341 has been provided.

Oath/Declaration

Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

Page 3 of the oath contains alterations that need to be initialed and dated.

Preliminary Amendment

The preliminary amendment filed January 17, 2006 and June 10, 2005 have been entered.

Drawings

Drawings filed June 10, 2005 have been accepted.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 26, 33-34 and 36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In **claim 26** applicants have recited a gene encoding a StarD10 [sic] (polypeptide); however applicants are not in possession of the said gene. In fact

applicants are only in possession of the cDNA that encodes the said polypeptide. A gene comprises promoter nucleotide sequences and intron and exon nucleotide sequences, which the applicants have not provided any written description for. Presently applicants lack written description for the gene encoding the StarD10 (polypeptide).

Claims 33-34 and 36 are dependent claims that do not remedy the deficiencies of the independent claims that they are dependent therefrom.

Claims 26, 33-34 and 36 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for detecting the presence of a cancerous breast epithelial cell in a subject or in a biological sample from said subject, said method comprising screening the level of an expression product of a nucleic acid sequence encoding a StarD10 polypeptide comprising a specific amino acid in said biological sample, wherein an elevated level of said expression product in said sample compared to a normal level of said expression product when no cancerous breast epithelial cells are present is indicative of the presence of said a cancerous breast epithelial cell, does not reasonably provide enablement for a method for detecting the presence of an aberrant cell in a subject or in a biological sample from said subject, said method comprising screening the level of an expression product of a gene encoding a StarD10 in said biological sample, wherein an elevated level of said expression product in said sample compared to a normal level of said expression product when no aberrant cells are present is indicative of the presence of said an aberrant cell. The specification does not enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir.1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the breadth of the claims, (2) the nature of the invention, (3) the state of the prior art, (4) the predictability or unpredictability of the art, (5) the relative skill of those in the art, (6) the amount or direction or guidance presented, (7) the presence or absence of working examples, and (8) the quantity of experimentation necessary. Although the quantity of experimentation alone is not dispositive in a determination of whether the required experimentation is undue, this factor does play a central role. For example, a very limited quantity of experimentation may be undue in a fledgling art that is unpredictable where no guidance or working examples are provided in the specification and prior art, whereas the same amount of experimentation may not be undue when viewed in light of some

guidance or a working example or the experimentation required is in a predictable established art. Conversely, a large quantity of experimentation would require a correspondingly greater quantum of guidance, predictability and skill in the art to overcome classification as undue experimentation. In Wands, the determination that undue experimentation was not required to make the claimed invention was based primarily on the nature of the art, and the probability that the required experimentation would result in successfully obtaining the claimed invention. (Wands, 8 USPQ2d 1406). Thus, a combination of factors which, when viewed together, would provide an artisan of ordinary skill in the art with an expectation of successfully obtaining the claimed invention with additional experimentation would preclude the classification of that experimentation as undue. A combination of Wands factors, which provide a very low likelihood of successfully obtaining the claimed invention with additional experimentation, however, would render the additional experimentation undue.

1-2 .Breadth of the claims and the nature of the invention..

In regards to the method of the invention and the breadth of the claims the broadest interpretation that applies is a method for detecting the presence of an aberrant cell in a subject or in a biological sample from said subject, said method comprising screening the level of an expression product of a gene encoding a StarD10 in said biological sample, wherein an elevated level of said expression product in said sample compared to a normal level of said expression product when no aberrant cells are present is indicative of the presence of said an aberrant cell.

3-4. The state of prior art and the level of predictability in the art.

The level of predictability is low in the art with regards to the broad scope of the claimed method of the invention. There are no references or published documents that discuss an expression product of a gene encoding a StarD10 in any cancerous cells; however various references disclose an amino acid sequence that is 100% identical to the amino acid sequence of SEQ ID NO:5 (presumably StarD 10) and as mentioned above, without any reference to cancer, cancerous cells or even breast epithelial cells.

Lai et al., 2000 disclose an amino acid sequence that is 100% identical to the amino acid sequence of SEQ ID NO: 5 and teach that modern biomedical research greatly benefits from large-scale genome-sequencing projects ranging from studies of viruses, bacteria, and yeast to multicellular organisms, like *Caenorhabditis elegans*. Comparative genomic studies offer a vast array of prospects for identification and functional annotation of human ortholog genes. A novel comparative proteomic approach for assembling human gene contigs and assisting gene discovery was presented. The *C. elegans* proteome was used as an alignment template to assist in novel human gene identification from human EST nucleotide databases. Among the available 18,452 *C. elegans* protein sequences, our results indicate that at least 83% (15,344 sequences) of *C. elegans* proteome has human homologous genes, with 7,954 records of *C. elegans* proteins matching known human gene transcripts. Only 11% or less of *C. elegans* proteome contains nematode-specific genes. It was found that the remaining 7,390 sequences might lead to discoveries of novel human genes, and over 150 putative full-length human gene transcripts were assembled upon further database analyses.

Yamanaka et al., 2000 disclose an amino acid sequence that is 100% identical to the amino acid sequence of SEQ ID NO: 5 and report a novel gene that is specifically expressed in haploid germ cells isolated from a subtracted cDNA library of mouse testis A cDNA-encoded phospatidylcholine transfer protein (PCTP)-like protein (PCTP-L) was present predominantly at the flagella in elongated spermatids through to sperm. The stage-specific expression of PCTP-L and specific localization in sperm flagellum suggest that it has specific roles in sperm maturation or fertilization.

5. The relative skill in the art.

The relative skill in the art as it relates to the method of the invention is characterized by that of a M.D. or Ph. D. level individual.

6-7. The amount of guidance present and the existence of working examples.

The applicants have provided limited guidance with regards to the claimed method of the invention; specifically applicants have disclosed experiments on pages of the specification that would suggest the over expression of StarD10 in primary breast epithelial cell tissue culture that are cancerous cells. However, there are no experiments or guidance that would indicate the over-expression of StarD10 in other types cancerous cells or tissue.

8. The quantity of experimentation necessary.

The amount of experimentation that is required is undue: while a method for detecting the presence of a cancerous breast epithelial cell in a subject or in a biological sample from said subject, said method comprising screening the level of an expression product of a nucleic acid sequence encoding a StarD10 polypeptide comprising a

specific amino acid in said biological sample, wherein an elevated level of said expression product in said sample compared to a normal level of said expression product when no cancerous breast epithelial cells are present is indicative of the presence of said a cancerous breast epithelial cell might be considered routine, a method of a method for detecting the presence of an aberrant cell in a subject or in a biological sample from said subject, said method comprising screening the level of an expression product of a gene encoding a StarD10 in said biological sample, wherein an elevated level of said expression product in said sample compared to a normal level of said expression product when no aberrant cells are present is indicative of the presence of said an aberrant cell is not routine and requires more experimentation. Therefore, in view of the overly broad scope of the claims, the lack of guidance and working examples provided in the specification, and the high degree of unpredictability as evidenced by the prior art, undue experimentation would be necessary for a skilled artisan to make and use the entire scope of the claimed invention.

It must be noted that the issue in this case is the breath of the claims in light of the predictability of the art as determined by the number of working examples, the skill level of the artisan and the guidance presented in the instant specification and the prior art of record. The Applicants make and test position is inconsistent with the decisions of *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) where it is stated that "... scope of claims must bear a reasonable correlation to scope of enablement provided by the specification to persons of ordinary skill in the art...". Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the

experimentation left to those skilled in the art is unnecessarily and improperly extensive and undue. See *In re Wands*, 858 F.2d at 737, 8 USPQZd at 1404 (Fed. Cir. 1988). Therefore, for the instant specification to be enabling, it needs to provide direction/guidance regarding an acceptable number of different types of cancerous/aberrant cells.

Absent sufficient guidance/direction one of skill in the art would not be able to practice the claimed invention commensurate in scope with the claims. Thus, for all these reasons, the specification is not considered to be enabling for one skilled in the art to make and use the claimed invention as the amount of experimentation required is undue, due to the broad scope of the claims, the lack of guidance and insufficient working examples provided in the specification and the high degree of unpredictability as evidenced by the state of the prior art, attempting to test all the different type cancerous/aberrant cells encompassed by the claimed invention would constitute undue experimentation. Therefore, applicants have not provided sufficient guidance to enable one of skill in the art to make and use the claimed invention in a manner that reasonably correlates with the scope of the claims, to be considered enabling.

Claim 26, 33-34 and 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

"StarD10" appears to be a laboratory designation and a search of all known data bases that the examiner uses to perform his duties revealed no specific information with regards to the phrase "StarD10". Most likely the applicants are referring to a "novel"

polypeptide (not a well known protein with an undisputed well known amino acid sequence) in which case it is pertinent that the applicants amend the claim in order to provide a SEQ ID NO: that clarifies what "StarD10" encompasses.

Claims 33-34 and 36 are dependent claims that do not further remedy the deficiencies of the independent claim that they are dependent therefrom.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert B. Mondesi whose telephone number is 571-272-0956. The examiner can normally be reached on 9am-5pm, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Robert B Mondesi
Examiner
Art Unit 1652

8-16-07